



THOMAS L. GARTHWAITE, M.D.
Director and Chief Medical Officer

FRED LEAF
Chief Operating Officer

COUNTY OF LOS ANGELES
DEPARTMENT OF HEALTH SERVICES
313 N. Figueroa, Los Angeles, CA 90012
(213) 240-8101

BOARD OF SUPERVISORS

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First District

Yvonne Brathwaite Burke
Second District


Zev Yaroslavsky
Third District

Don Knabe
Fourth District

Michael D. Antonovich
Fifth District

October 21, 2004

TO: Each Supervisor

FROM: Thomas L. Garthwaite, M.D. 
Director and Chief Medical Officer

SUBJECT: **NOTIFICATION OF DEPARTMENT OF HEALTH SERVICES USE OF DELEGATED
AUTHORITY TO ACCEPT AMENDMENT NO. 3 TO GRANT AGREEMENT NO. H18199
WITH THE UNIVERSITY OF SOUTHERN CALIFORNIA FOR TUBERCULOSIS TRIALS
PATIENT STUDIES**

This is to advise you that the Department of Health Services (DHS or Department) will exercise its delegated authority, as approved by the Board of Supervisors on August 29, 2000 (see attached adopted Board letter), authorizing the Director, or his designee, to accept amendments to the above referenced grant agreement for future year funding allocations, not to exceed a total of \$1,104,270, from September 23, 1999 through September 22, 2009.

On August 16, 2001 and December 2, 2003, the Department notified the Board that it would exercise its delegated authority and accept Amendments No. 1 and 2, respectively, to Grant Agreement No. H18199. Amendment No. 1 extended the period of performance from September 23, 2000 through September 22, 2002. Amendment No. 2 extended the period of performance through September 22, 2003.

Accordingly, the Department will accept the attached Amendment No. 3 to Grant Agreement No. H18199 with the University of Southern California in the amount of \$72,598. Amendment No. 3 increases the total grant amount to \$392,268 and extends the period of performance from September 23, 2003 through September 22, 2004.

DHS anticipates receipt of an additional amendment from the University of Southern California for funding for the period of September 23, 2004 through September 22, 2005.

If you have any questions or require additional information, please let me know.

TLG:ma
tbtrialshd#3.mem.wpd

Attachments (2)

c: Chief Administrative Officer
County Counsel
Executive Officer, Board of Supervisors



→ **MARK FINUCANE, Director**

COUNTY OF LOS ANGELES
DEPARTMENT OF HEALTH SERVICES
313 N. Figueroa, Los Angeles, CA 90012

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August 17, 2000

ADOPTED
BOARD OF SUPERVISORS
COUNTY OF LOS ANGELES

Honorable Board of Supervisors
County of Los Angeles
383 Kenneth Hahn Hall of Administration
500 West Temple Street
Los Angeles, California 90012

88

AUG 29 2000

Violet Varona-Lukens
VIOLET VARONA-LUKENS
EXECUTIVE OFFICER

Dear Supervisors:

TUBERCULOSIS TRIALS CONSORTIUM GRANT AWARD FROM THE UNIVERSITY OF SOUTHERN CALIFORNIA (All Districts) (3 Votes)

IT IS RECOMMENDED THAT YOUR BOARD:

1. Accept a grant award (Exhibit I) from the University of Southern California (USC) in the amount \$96,326, for the provision of active and latent tuberculosis infection patient studies, effective September 23, 1999 through September 22, 2000.
2. Delegate authority to the Director of Health Services or his designee to execute amendments to the USC grant award, accepting future year funding allocations, on behalf of the County of Los Angeles, not to exceed \$1,104,270, effective September 23, 1999 through September 22, 2009.

PURPOSE OF THE RECOMMENDED ACTIONS:

In approving these actions, the Board is:

- accepting a grant award from USC for the Tuberculosis (TB) Trials Consortium project in the amount of \$96,326, effective September 23, 1999 through September 22, 2000.
- authorizing the Director of Health Services, or his designee, to seek and execute amendments to the USC grant award, extending the term through September 22, 2009, with total future year allocations not to exceed \$1,007,944.

JUSTIFICATION:

The Department of Health Services (DHS) is recommending approval of these actions to assist the Federal Centers for Disease Control and Prevention (CDC) in evaluating new tests or approaches for the diagnosis of TB infection and disease.

FISCAL IMPACT:

There are no net County costs. The total program cost of \$96,326 is 100% offset by the USC grant award.

FINANCING:

Funding is included in the Fiscal Year 2000-2001 Adopted County Budget, and will be requested as a continuing appropriation in subsequent fiscal years contingent upon the award of grant funds.

FACTS AND PROVISIONS/LEGAL REQUIREMENTS:

On September 23, 1999, USC entered into an agreement with the CDC for the provision of a TB Trials Consortium. The CDC funded project requires that USC concurrently perform multiple studies and/or clinical trials for the treatment of active TB, for the prevention of active TB in persons with latent TB infection and for the evaluation of new tests or approaches for the diagnosis of TB infection and disease. DHS was identified by USC as one of the TB Trials Consortium project sites.

The USC grant award provides funding support to DHS for the provision of active TB and latent TB patient studies at the Central Public Health Center.

Each treatment protocol implemented locally by the consortium is submitted to the Institutional Review Board for approval at USC and at the CDC.

Attachment A provides additional information.

County Counsel has approved the grant award (Exhibit I) as to form.

CONTRACTING PROCESS:

It is not appropriate to advertise grant awards to the County on the Office of Small Business' Countywide Web Site.


IMPACT ON CURRENT SERVICES (OR PROJECTS):

There is no impact on current DHS services.

Honorable Board of Supervisors
August 17, 2000
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When approved, this Department requires three signed copies of the Board's action.

Respectfully submitted,


Mark Finucane
Director of Health Services

MF:dhh

Attachments

c: Chief Administrative Officer
County Counsel
Executive Officer, Board of Supervisors

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SUMMARY OF GRANT AWARD1. TYPE OF SERVICE:

Implementation of a Tuberculosis (TB) Trials Consortium for the provision of active and latent tuberculosis infection patient studies at the Central Public Health Center.

2. AGENCY ADDRESS AND CONTACT PERSON:

University of Southern California
Division of Infectious Diseases
1200 North State Street, GNH 6442
Los Angeles, California 90033
Attention: Brenda Jones, M.D., Principal Investigator
Telephone: (323) 343-8288

3. TERM:

Project Term: September 23, 1999 through September 22, 2009
Budget Term: September 23, 1999 through September 22, 2000

4. FINANCIAL INFORMATION:

Personnel Salaries:	\$ 63,878
Employee Benefits:	16,745
Indirect Costs:	<u>15,703</u>

Total Budget	\$ 96,326
Less: USC Award	<u>96,326</u>
Net County Costs	- 0 -

5. SERVICE INFORMATION:

Estimated study of 50 patients per year, 15 patients with active TB and 35 patients with latent TB infection.

6. GEOGRAPHIC AREA TO BE SERVED:

Countywide.

7. DESIGNATED ACCOUNTABLE FOR PROJECT MONITORING:

Dr. James Haughton, Medical Director, Public Health Programs and Services

8. APPROVALS:

Public Health Programs and Services

Jonathan Fielding, M.D., Director

Contracts and Grants Division:

John H. Ricks, Chief

County Counsel (approval as to form):

Rosemarie Belda, Senior Deputy

AMENDMENT NO. 3

CONSORTIUM AGREEMENT

Between

UNIVERSITY OF SOUTHERN CALIFORNIA

And

LOS ANGELES COUNTY DEPARTMENT OF HEALTH SERVICES

AGREEMENT NO. H18199

The purpose of this amendment to Agreement No. H18199, issued under Prime Contract No. 200-1999-00096 from the Centers for Disease Control and Prevention, is to increase and extend this agreement, revise the work statement and modify Article I. The changes to this agreement are as follows:

ARTICLE I - PERFORMANCE AND DELIVERY

A. STATEMENT OF WORK:

A revised Exhibit A – Statement of Work is incorporated herein.

B. PERIOD OF PERFORMANCE:

The Period of Performance is modified to read 9/23/99 through 9/22/04.

C. ESTIMATED COST:

The Estimated Cost is increased by \$72,598.00 from \$319,670.00 to a new total of \$392,268.00. Exhibit B - Cost Estimate is incorporated herein.

All other Terms and Conditions remain unchanged.

IN WITNESS WHEREOF, the parties hereto have executed this Amendment in duplicate by duly authorized persons.

LOS ANGELES COUNTY
DEPARTMENT OF HEALTH SERVICES


By: _____

Name: _____

Title: _____

Date: _____

UNIVERSITY OF SOUTHERN CALIFORNIA

By:  _____

Name: Nolan Gomm
Deputy Director

Title: Department of Contracts and Grants

Date: 8-9-2004

Exhibit A

Statement of Work

We propose a study of 100 patients per year (15 patients with active TB and 85 patients with latent TB infection). USC will initially “partner” with the Central Health Center, which is located 3 miles from the USC Study Site.

The majority of active TB patients will be identified for enrollment at the LAC+USC Medical Center. HIV positive patients will be followed in the HIV Clinic at USC, where Dr. Jones will be the primary care provider. HIV negative patients will be followed at the Central Health Center, where Dr. Alvin Chin will be the primary care provider. The majority of patients with latent TB infection will be identified and followed at the Central Health Center.

Angela Grbic, R.N. and Bonnie Oamar M.D., R.N., are currently the Study Coordinators. In addition to their roles as the primary research nurses at USC, Angela Grbic and Bonnie Oamar will provide quality assurance for all data collected from USC and TB Control (Central Health Center). They will be in charge of recording and submitting data to the CDC for the enrollment and follow-up of study patients. Angela Grbic and Bonnie Oamar will also provide training and assistance to nurses based at the Central Health TB Clinic.

Regular meetings will take place between the staff at USC, TB Control, and the Central Health Center. Dr. Annette Nitta, the Director of TB Control is a Co-Investigator. Dr. Moon Kim is the Assistant Medical Director of the LA County TB Control program. She will coordinate efforts to identify and locate potential study participants at the Central Health Center. She will provide clinical consultation to the Central Health Center. Effective February 1, 2004, Dr. Christine Wigen will assume these responsibilities.

EXHIBIT B

Cost Estimate

9/23/03 through 9/22/04

Contract No. 200-1999-00096

Key Investigator: Annette Nitta, M.D.

<u>Name</u>	<u>Role on Project</u>	<u>% Effort</u>	<u>Hours</u>	<u>Salary</u>	<u>Fringe</u> <u>(40.0659%)</u>	<u>Total</u>
Annette Nitta, M.D.	Co-PI	2	42	\$ -0-	-0-	\$ -0-
Moon Kim, M.D*.	Co-PI	2	42	748	300	1,048
Christine Wigen, M.D.*	Co-PI	2	42	1,350	541	1,891
Han Wu, Ph.D.	Epidemiologist	2	42	1,274	510	1,784
Ermelinda Rayos, C.W.	Sr. Comm. Worker	100	2080	<u>39,184</u>	<u>15,699</u>	<u>54,883</u>
Direct Costs				\$42,556	\$17,050	\$59,606
Indirect Costs (21.7971%)						<u>12,992</u>
Total Costs 9/23/03 – 9/22/04						\$72,598

*Dr. Wigen replaced Dr. Kim effective 2/1/04